K080184

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

MAR 2 6 2008

NAME OF FIRM:
I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT:
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME:
Distal Humeral Plates with Angular Stability

COMMON NAME:
Bone Plate System

CLASSIFICATION:
Plate, Fixation, Bone

(see 21 CRF, Sec. 888.3030).

DEVICE PRODUCT CODE:
HRS

SUBSTANTIALLY EQUIVALENT DEVICES
Synthes 3.5mm LCP Distal Humerus System **(K033995)**
Acumed Congruent Bone Plate System **(K012655), (K063460), (K071715)**
Zimmer Periarticular Locking Plates and Screws **(K040593)**

DEVICE DESCRIPTION:
The I.T.S. GmbH Distal Humeral Plates with Angular Stability is a fracture fixation plating system for repairing factures located in the distal area of the humerus in the elbow (in the area of medial and lateral epicondyles of the distal humerus). The Distal Humeral Plates consist of two plate designs as a medial (8 hole) and dorsolateral (5 hole) left and right plate configuration - anatomically pre-contoured to fit the distal humerus human anatomy and manufactured from Commercialy Pure (CP) Titanium material for minor intra-operative forming by the surgeon. The offset opposite location of the plates on the medial and lateral epicondyles provide a girder-like construct for difficult bone fracture reconstruction stability. The added benefit of locking screws within each plate and up to a +- 15^0 angle position allows a fixed-angle contruct of screw-to-plate and offers angle-flexibility in screw positioning for further optimal fracture stability. Small holes in the plate allow intermediate 'k-wire bone fracture segment positioning' for reducing and aligning the fracture bone segments while positioning the plates and introducing multiple sizes of locking/non-locking screws as needed for stabilizing the fracture(s)

– when using optional x-ray fluroscopy. The system offers a 3.5mm locking and non-locking cortical screw and a 4.2mm locking cancellous screw in multiple lengths manufactured from High Strength 6-4 Alloyed Titanium material. All plates and screws are processed with a TIODIZE II surface treatment – which improves the material surface hardness and biocompatibility to adjacent tissues. The low-profile and contoured left and right plate design minimizes soft-tissue irritation for the patient. A full compliment of instrumentation is available for use with the system.

INTENDED USE:

The ***intended use*** of the I.T.S. Distal Humeral Plates with Angular Stability is to stabilize fractures of the distal humerus in the elbow of a pediatric or adult patient.

Indications for use include intra-articular fractures, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The I.T.S. Distal Humeral Plates with Angular Stability is substantially equivalent to the Synthes and Acumed distal humeral bone plate systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. Distal Humeral Plates with Angular Stability is shown to be safe and effective for use in fracture fixation of the distal humerus in the elbow.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2008

I.T.S. GmbH
% Engineering Consulting Services, Inc.
Mr. Al Lippincott
Official Correspondent
3150 East 200th Street
Prior Lake, MN 55372

Re: K080184
Trade/Device Name: Distal Humeral Plates with Angular Stability
Regulation Number: 21 CFR 888.3030
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: January 18, 2008
Received: January 25, 2008

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

I.T.S.

Indications for Use

510(k) NUMBER: _____

DEVICE NAME: **DISTAL HUMERAL PLATES WITH ANGULAR STABILITY**

INDICATIONS FOR USE:

The I.T.S. Distal Humeral Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the distal humerus in the elbow of a pediatric or adult patient.

Indications for Use include intra-articular fractures, supracondylar fractures, osteotomies, and non-unions of the distal humerus.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Section XI

510(k) Number K080184

I.T.S.
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